Lisa Medley/DC/USEPA/US
10/03/2007 02:57 PM

To NCIC HPV@EPA
cc
bcc
Subject Fw: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

"Saifi, Zahra" <Zahra_Saifi@americanchemistry.com>
10/02/2007 10:21 AM

To Louis Scarano/DC/USEPA/US@EPA
cc NCIC OPPT@EPA, Rtk Chem@EPA
Subject FW: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

Zahra Saifi
Coordinator
American Chemistry Council
1300 Wilson Blvd
Arlington, VA 22209
Phone: 703/741-5632
Fax: 703/741-6091
E-mail: zahra_saifi@americanchemistry.com

From: Saifi, Zahra
Sent: Tuesday, October 02, 2007 10:17 AM
To: 'Scarano.Louis@epamail.epa.gov'
Subject: FW: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

Good Morning Mr. Scarano;

Attached are the two documents you requested.

Please feel free to contact me if you have any questions.

Thank you
Have a nice day

Zahra Saifi
Coordinator
American Chemistry Council
1300 Wilson Blvd

Arlington, VA 22209
Phone: 703/741-5632
Fax: 703/741-6091/6632
E-mail: zahra_saifi@americanchemistry.com

Actions taken on EPA's phthalate test plan comments - embeded in EPA comments.doc

Actions Taken on EPA Comments on TM Test Plan - embeded in EPA comments.doc

201-16442

Phthalate Esters Panel Test Plans for Phthalate HPV registration number ; Reply to EPA Comments

EPA COMMENTS ON CHEMICAL RTK HPV CHALLENGE SUBMISSION: PHTHALATE ESTERS CATEGORY

SUMMARY OF EPA COMMENTS

The sponsor, the Phthalate Esters Panel HPV Testing Group of the American Chemistry Council, submitted a test plan and robust summaries for the Phthalate Esters Category dated December 14, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 20, 2002. EPA has reviewed this submission and reached the following conclusions:

1. Category Justification. The submitter's rationale for selecting and subdividing the category is reasonable for the purposes of the HPV Challenge Program.

2. Physicochemical Properties and Environmental Fate. The physicochemical, photodegradation, and water stability data provided by the submitter are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide biodegradation data for 8 of the 18 sponsored phthalates and data inputs for its transportation and distribution models.

Comment [daw1]: New biodegradation robust study summaries have been added to various dossiers, previously submitted biodegradation summaries in various dossiers have been updated according to comments by EPA, and previously submitted summaries have been enhanced with additional information. Sufficient data are now provided to adequately characterize the biodegradation potential of all phthalate ester substances in this category. See specific comments below.

Action/Comments

New biodegradation robust study summaries have been added to various dossiers, previously submitted biodegradation summaries in various dossiers have been updated according to comments by EPA, and previously submitted summaries have been enhanced with additional information. Sufficient data are now provided to adequately characterize the biodegradation potential of all phthalate ester substances in this category. See specific comments below.

3. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program.

4. Ecological Effects. For the most part, acute and chronic data for the category phthalates are adequate, although missing data elements need to be added to the robust summaries.

Comment [daw2]: Available missing data elements for select studies were added to robust summaries. See specific comments below.

Action/Comments

Available missing data elements for select studies were added to robust summaries. See specific comments below.

Three transitional phthalates (dihexyl phthalate, diheptyl phthalate and diisoheptyl phthalate) are inadequately represented by DEHP because their physicochemical properties are sufficiently different from those of DEHP to suggest a chronic aquatic toxicity concern. EPA suggests that the submitter conduct a chronic daphnid test on one of these phthalates.

Comment [daw3]: Invertebrate and/or fish chronic data are available for dihexyl phthalate, diisoheptyl phthalate, C7-11 phthalate, C7-9 phthalate, diisononyl phthalate, diisodecyl phthalate, diisoundecyl phthalate, and diisotricecyl phthalate. Robust study summaries have been prepared and added to respective dossiers for these substances.

Action/Comments

Invertebrate and/or fish chronic data are available for dihexyl phthalate, diisoheptyl phthalate, C7-11 phthalate, C7-9 phthalate, diisononyl phthalate, diisodecyl phthalate, diisoundecyl phthalate, and diisotricecyl phthalate. Robust study summaries have been prepared and added to respective dossiers for these substances.

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.

EPA COMMENTS ON THE PHTHALATE ESTERS CATEGORY CHALLENGE SUBMISSION

General

The submitter presented a thorough and well-written test plan. Although the submitter did not provide robust summaries for all cited studies, those missing were not critical to the overall category assessment.

Category Definition

The submitter proposed a category of 18 single and mixed phthalates whose identities and CAS numbers are listed in the submission. They are broadly defined as 1,2-benzenedicarboxylic acids with side chain esters ranging in carbon chain length from C1 to C13. The phthalates were subdivided into three groups based on their physicochemical and toxicological properties: (1) low molecular weight (LMW) phthalates produced from alcohols with straight-chain carbon backbones of <3, (2) transitional phthalates produced from alcohols with straight-chain carbon backbones of C4-6, and (3) high molecular weight (HMW) phthalates produced from alcohols with straight-chain carbon backbones of >/=C7 or a ring structure. Supporting data on 10 non sponsored phthalates are included for the transitional and HMW phthalates. The category definition is clearly stated.

While the category definition is reasonable for the purposes of the HPV Challenge Program, higher tiered test results may alter the category definition in the future.

Category Justification

The submitter based the category on fundamentally similar chemical structures--all members are diesters of phthalic acid–and subdivided the category into three groups based on similar physicochemical and toxicological properties. The rationale for the makeup of the category and each subcategory is reasonable for the purposes of the HPV Challenge Program; however, butyl benzyl phthalate (BBP, CAS No. 85-68-7) and diisooctyl phthalate (DIOP, CAS No. 27554-26-3) should be moved from the transitional subcategory to the HMW subcategory because the former substance has a ring structure and the latter has a C7 backbone.

Action/Comments

Although the high molecular weight subcategory is defined in part as including phthalates that can contain a benzyl group, it was not the original intent of the Phthalates Panel to include butyl benzyl phthalate (BBP, CAS No. 85-68-7) in this category although it contains a benzyl group. To correct this misunderstanding, the subcategory definition will be clarified to include the following: This subcategory also includes a phthalate with a benzyl group and a second group composed of a diester with combined alkyl groups totaling ≥C7.
The Transitional subcategory definition was also clarified as follows: This subcategory also includes phthalates produced from benzyl alcohol as one ester group with the second ester composed of an alkyl group having a carbon backbone of C4 to C6. This clarification will allow the inclusion of BBP in this category.
It was also the original intent of the Phthalates Panel to include diisooctyl phthalate (DIOP, CAS No. 27554-26-3) in the Transitional subcategory. The rationale for its inclusion is structure based. EPA may have mistakenly thought it appropriate for DIOP's inclusion in the high molecular weight subcategory because the EPI SuiteTM computer model represents the alkyl group structures of this substance as containing a C7 backbone. However, this substance can have alkyl groups with dimethyl hexyl groups and it may also be possible that it shares human health effects consistent with select other members of this category even though specific data for DIOP do not exist. Therefore, the reasoning to keep DIOP in the Transitional subcategory is consistent with retaining select other members of this category that do not

Comment [daw4]: Although the high molecular weight subcategory is defined in part as including phthalates that can contain a benzyl group, it was not the original intent of the Phthalates Panel to include butyl benzyl phthalate (BBP, CAS No. 85-68-7) in this category although it contains a benzyl group. To correct this misunderstanding, the subcategory definition will be clarified to include the following: This subcategory also includes a phthalate with a benzyl group and a second group composed of a diester with combined alkyl groups totaling ≥C7.
The Transitional subcategory definition was also clarified as follows: This subcategory also includes phthalates produced from benzyl alcohol as one ester group with the second ester composed of an alkyl group having a carbon backbone of C4 to C6. This clarification will allow the inclusion of BBP in this category.
It was also the original intent of the Phthalates Panel to include diisooctyl phthalate (DIOP, CAS No. 27554-26-3) in the Transitional subcategory. The rationale for its inclusion is structure based. EPA may have mistakenly thought it appropriate for DIOP's inclusion in the high molecular weight subcategory because the EPI SuiteTM computer model represents the alkyl group structures of this substance as containing a C7 backbone. However, this substance can have alkyl groups with dimethyl hexyl groups and it may also be possible that it shares human health effects consistent with select other members of this category even though specific data for DIOP do not exist. Therefore, the reasoning to keep DIOP in the Transitional subcategory is consistent with retaining select other members of this category that do not have human health effects data that definitively show effects, but are assessed as having the potential to exhibit effects.

201-16642

Lisa Medley/DC/USEPA/US
10/03/2007 02:57 PM

To NCIC HPV@EPA
cc
bcc
Subject Fw: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

"Saifi, Zahra" <Zahra_Saifi@americanchemistry.com>
10/02/2007 10:21 AM

To Louis Scarano/DC/USEPA/US@EPA
cc NCIC OPPT@EPA, Rtk Chem@EPA
Subject FW: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

Zahra Saifi
Coordinator
American Chemistry Council
1300 Wilson Blvd
Arlington, VA 22209
Phone: 703/741-5632
Fax: 703/741-6091
E-mail: zahra_saifi@americanchemistry.com

From: Saifi, Zahra
Sent: Tuesday, October 02, 2007 10:17 AM
To: 'Scarano.Louis@epamail.epa.gov'
Subject: FW: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

Good Morning Mr. Scarano;

Attached are the two documents you requested.

Please feel free to contact me if you have any questions.

Thank you
Have a nice day

Zahra Saifi
Coordinator
American Chemistry Council
1300 Wilson Blvd

Arlington, VA 22209
Phone: 703/741-5632
Fax: 703/741-6091/6632
E-mail: zahra_saifi@americanchemistry.com

Actions taken on EPA's phthalate test plan comments - embeded in EPA comments.doc

Actions Taken on EPA Comments on TM Test Plan - embeded in EPA comments.doc

201-16642

Phthalate Esters Panel Test Plans for Phthalate HPV registration number ; Reply to EPA Comments

EPA COMMENTS ON CHEMICAL RTK HPV CHALLENGE SUBMISSION: PHTHALATE ESTERS CATEGORY

SUMMARY OF EPA COMMENTS

The sponsor, the Phthalate Esters Panel HPV Testing Group of the American Chemistry Council, submitted a test plan and robust summaries for the Phthalate Esters Category dated December 14, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 20, 2002. EPA has reviewed this submission and reached the following conclusions:

1. Category Justification. The submitter's rationale for selecting and subdividing the category is reasonable for the purposes of the HPV Challenge Program.

2. Physicochemical Properties and Environmental Fate. The physicochemical, photodegradation, and water stability data provided by the submitter are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide biodegradation data for 8 of the 18 sponsored phthalates and data inputs for its transportation and distribution models.

Comment [daw1]: New biodegradation robust study summaries have been added to various dossiers, previously submitted biodegradation summaries in various dossiers have been updated according to comments by EPA, and previously submitted summaries have been enhanced with additional information. Sufficient data are now provided to adequately characterize the biodegradation potential of all phthalate ester substances in this category. See specific comments below.

Action/Comments

New biodegradation robust study summaries have been added to various dossiers, previously submitted biodegradation summaries in various dossiers have been updated according to comments by EPA, and previously submitted summaries have been enhanced with additional information. Sufficient data are now provided to adequately characterize the biodegradation potential of all phthalate ester substances in this category. See specific comments below.

3. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program.

4. Ecological Effects. For the most part, acute and chronic data for the category phthalates are adequate, although missing data elements need to be added to the robust summaries.

Comment [daw2]: Available missing data elements for select studies were added to robust summaries. See specific comments below.

Action/Comments

201-16642

Lisa Medley/DC/USEPA/US
10/03/2007 02:57 PM

To NCIC HPV@EPA
cc
bcc
Subject Fw: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

"Saifi, Zahra" <Zahra_Saifi@americanchemistry.com>
10/02/2007 10:21 AM

To Louis Scarano/DC/USEPA/US@EPA
cc NCIC OPPT@EPA, Rtk Chem@EPA
Subject FW: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

Zahra Saifi
Coordinator
American Chemistry Council
1300 Wilson Blvd
Arlington, VA 22209
Phone: 703/741-5632
Fax: 703/741-6091
E-mail: zahra_saifi@americanchemistry.com

From: Saifi, Zahra
Sent: Tuesday, October 02, 2007 10:17 AM
To: 'Scarano.Louis@epamail.epa.gov'
Subject: FW: Request for ACC Response to EPA Comments on Phthalate Esters Category for the HPV Program

Good Morning Mr. Scarano;

Attached are the two documents you requested.

Please feel free to contact me if you have any questions.

Thank you
Have a nice day

Zahra Saifi
Coordinator
American Chemistry Council
1300 Wilson Blvd

Arlington, VA 22209
Phone: 703/741-5632
Fax: 703/741-6091/6632
E-mail: zahra_saifi@americanchemistry.com

Actions taken on EPA's phthalate test plan comments - embeded in EPA comments.doc

Actions Taken on EPA Comments on TM Test Plan - embeded in EPA comments.doc

201-16642

Phthalate Esters Panel Test Plans for Phthalate HPV registration number ; Reply to EPA Comments

EPA COMMENTS ON CHEMICAL RTK HPV CHALLENGE SUBMISSION: PHTHALATE ESTERS CATEGORY

SUMMARY OF EPA COMMENTS

The sponsor, the Phthalate Esters Panel HPV Testing Group of the American Chemistry Council, submitted a test plan and robust summaries for the Phthalate Esters Category dated December 14, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 20, 2002. EPA has reviewed this submission and reached the following conclusions:

1. Category Justification. The submitter's rationale for selecting and subdividing the category is reasonable for the purposes of the HPV Challenge Program.

2. Physicochemical Properties and Environmental Fate. The physicochemical, photodegradation, and water stability data provided by the submitter are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide biodegradation data for 8 of the 18 sponsored phthalates and data inputs for its transportation and distribution models.

Comment [daw1]: New biodegradation robust study summaries have been added to various dossiers, previously submitted biodegradation summaries in various dossiers have been updated according to comments by EPA, and previously submitted summaries have been enhanced with additional information. Sufficient data are now provided to adequately characterize the biodegradation potential of all phthalate ester substances in this category. See specific comments below.

Action/Comments

New biodegradation robust study summaries have been added to various dossiers, previously submitted biodegradation summaries in various dossiers have been updated according to comments by EPA, and previously submitted summaries have been enhanced with additional information. Sufficient data are now provided to adequately characterize the biodegradation potential of all phthalate ester substances in this category. See specific comments below.

3. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program.

4. Ecological Effects. For the most part, acute and chronic data for the category phthalates are adequate, although missing data elements need to be added to the robust summaries.

Comment [daw2]: Available missing data elements for select studies were added to robust summaries. See specific comments below.

Action/Comments

have human health effects data that definitively show effects, but are assessed as having the potential to exhibit effects.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility)

The data provided by the submitter are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation and stability in water are adequate for the purposes of the HPV Challenge Program.
Biodegradation. In several cases EPA identified important information not cited by the submitter. Robust summaries need to be submitted for these studies to complete the public record for the category.

Comment [daw5]: New biodegradation robust study summaries have been added and additional information has been added to select existing summaries to complete the public record.

Action/Comments

New biodegradation robust study summaries have been added and additional information has been added to select existing summaries to complete the public record.

The submitter provided adequate data for only three of the 18 HPV chemicals. These are:

(1) Dimethyl phthalate (DMP, CAS No. 131-11-3)
(2) Diethyl phthalate (DEP, CAS No. 84-66-2)

Comment [daw6]: The biodegradation robust summaries for dimethyl and diethyl phthalates were updated to reflect that the method used for both did not allow characterizing these substances as readily biodegradable.

Action/Comments

The biodegradation robust summaries for dimethyl and diethyl phthalates were updated to reflect that the method used for both did not allow characterizing these substances as readily biodegradable

(3) 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (CAS No. 68515-50-4)

Comment [daw7]: Additional information was added to the robust summary for this substance to support its ready biodegradability characterization.

Action/Comments

Additional information was added to the robust summary for this substance to support its ready biodegradability characterization.

The submitter provided inadequate data for the following chemical:

(4) 1,2-Benzendicarboxylic acid, diundecyl ester (CAS No. 3648-20-2)

Comment [daw8]: New biodegradation data for this substance was added to the dossier. The data were developed using an unacclimated inoculum, which in conjunction with the acclimated data described in Saegar, V.W. and Tucker, E.S.; Appl. Environ. Microbiol. 31:29-34 (1976), will be adequate to characterize the biodegradability of this substance.

Action/Comments

New biodegradation data for this substance was added to the dossier. The data were developed using an unacclimated inoculum, which in conjunction with the acclimated data described in Saegar, V.W. and Tucker, E.S.; Appl. Environ. Microbiol. 31:29-34 (1976), will be adequate to characterize the biodegradability of this substance.

The submitter concluded that this chemical is readily biodegradable from the results of a modified Gledhill test. This conclusion is incorrect because the Gledhill test is not a test for ready biodegradation. However, EPA will consider it adequate in combination with information obtained from other sources (river die-away test, Saegar, V.W. and Tucker, E.S.; Appl. Environ. Microbiol. 31:29-34 (1976)).

Comment [daw9]: The ready biodegradable characterization was removed and the robust summary updated to reflect that the test was conducted under acclimated conditions.

Action/Comments

The ready biodegradable characterization was removed and the robust summary updated to reflect that the test was conducted under acclimated conditions.

The submitter provided inadequate data for the following chemical:

(5) Mixed decyl, hexyl, octyl diesters of 1,2-benzenedicarboxylic acid (610P, CAS No. 68648-93-1)

Comment [daw10]: There are acclimated biodegradation data for a di-C6, di-C8, and di-C711, in conjunction with unacclimated data for a di-C7, di-C9, and di-C10 that can be used as read-across to mixed decyl, hexyl, octyl phthalate ester. These data are in their respective dossiers.

Action/Comments

There are acclimated biodegradation data for a di- C6, di-C8, and di-C711, in conjunction with unacclimated data for a di-C7, di-C9, and di-C10 that can be used as read-across to mixed decyl, hexyl, octyl phthalate ester. These data are in their respective dossiers.

The submitter concluded that this chemical is readily biodegradable from the results of a modified Gledhill test. This conclusion is incorrect because the Gledhill test is not a test for ready biodegradation.

Comment [daw11]: The ready biodegradable characterization was removed and the robust summary updated to reflect that the test was conducted under acclimated conditions.

Action/Comments

The ready biodegradable characterization was removed and the robust summary updated to reflect that the test was conducted under acclimated conditions.

However, EPA will consider it adequate in combination with information that EPA obtained for CAS No. 117-84-0 (river die-away test, Ritsema, R et al.; Chemosphere, 18: 2161-2175 (1989)).

The submitter did not provide biodegradation data on the following three chemicals.

Comment [daw12]: Data are available to characterize the biodegradability of all three substances and have been either added to selected dossiers or appropriate read-across data have been identified. See specific comments below.

Action/Comments

Data are available to characterize the biodegradability of all three substances and have been either added to selected dossiers or appropriate read-across data have been identified. See specific comments below.

However, EPA will consider these adequately addressed by extrapolation from data provided on analogues.

(6) 1,2-Benzendicarboxylic acid, diheptyl ester, branched and linear (CAS No. 68515-44-6)

Comment [daw13]: The biodegradability for this substance can be assessed by the new data added to the dossier for Diisoheptyl phthalate (DIHP, CAS No. 71888-89-6). These data can also be used to support characterizing the biodegradability of other members of the category.

Action/Comments

The biodegradability for this substance can be assessed by the new data added to the dossier for Diisoheptyl phthalate (DIHP, CAS No. 71888-89-6). These data can also be used to support characterizing the biodegradability of other members of the category.

(7) Diisoheptyl phthalate (DIHP, CAS No. 71888-89-6)

Comment [daw14]: A new robust summary from a biodegradation test for this substance was added to the dossier for this CAS number.

Action/Comments

A new robust summary from a biodegradation test for this substance was added to the dossier for this CAS number.

(8) 1,2-Benzenedicarboxylic acid, didecyl ester (CAS No. 84-77-5)

Comment [daw15]: Biodegradation data from DIDP (CAS #68515-49-1) are used as read across to this C10 phthalate ester. Because CAS #68515-49-1 is a branched alkyl phthalate ester and CAS #84-77-5 is a linear alkyl phthalate ester, this is a conservative data read-across. As CAS #68515-49-1 is readily biodegradable, CAS #84-77-5 would also be expected to be readily biodegradable. The robust summary for CAS #68515-49-1 has been enhanced and can be found in the dossier for this CAS number.

Action/Comments

Biodegradation data from DIDP (CAS #68515-49-1) are used as read across to this C10 phthalate ester. Because CAS #68515-49-1 is a branched alkyl phthalate ester and CAS #84-77-5 is a linear alkyl phthalate ester, this is a conservative data read-across. As CAS #68515-49-1 is readily biodegradable, CAS #84-77-5 would also be expected to be readily biodegradable. The robust summary for CAS #68515-49-1 has been enhanced and can be found in the dossier for this CAS number.

The submitter did not provide biodegradation data on the following two chemicals; however, EPA identified adequate data from the sources cited below.

Comment [daw16]: Biodegradation data have been added for these two substances. See specific comments below.

Action/Comments

Biodegradation data have been added for these two substances. See specific comments below.

(9) 1,2-Benzenedicarboxylic acid, heptyl undecyl ester, branched and linear (CAS No. 111381-90-9)(river die-away study, primary biodegradation; Carson D.B. et at; Aquat. Toxicol. Risk Assess., 13th Vol. ASTM STP, 1096 pp 48-59 (1990)).

Comment [daw17]: A biodegradation study robust summary for this substance has been added to the dossier for this CAS number.

Action/Comments

A biodegradation study robust summary for this substance has been added to the dossier for this CAS number.

(10) 1,2-Benzenedicarboxylic acid, dioctyl ester (CAS No. 117-84-0) (river die-away study; Ritsema, R. et al. Chemosphere, 18:2161-2175 (1989)).

Comment [daw18]: Data for dioctyl phthalate ester developed by Ritsema et al. were summarized and added to the dossier for this substance.

Action/Comments

Data for dioctyl phthalate ester developed by Ritsema et al. were summarized and added to the dossier for this substance.

The submitter states on pages 23 and 24 of the test plan that there are adequate data for this endpoint and that additional testing is not required. EPA disagrees. The submitter needs to provide measured ready biodegradation data following OECD Guideline 301 for the following eight chemicals for the reasons given below:

Comment [daw19]: Adequate data are now available for all substances in this category. See specific comments below.

Action/Comments

Adequate data are now available for all substances in this category. See specific comments below.

(11) 1,2-Benzenedicarboxylic acid, diisooctyl ester (CAS No. 27554-26-3):

Comment [daw20]: A biodegradation study robust summary for this substance has been added to the dossier for this CAS number.

Action/Comments

A biodegradation study robust summary for this substance has been added to the dossier for this CAS number.

The submitter concluded that this chemical is readily biodegradable from the results of a modified Gledhill test. This conclusion is incorrect because the Gledhill test is not a test for ready biodegradation.

Comment [daw21]: The ready biodegradable characterization was removed and the robust summary updated to reflect that the test was conducted under acclimated conditions.

Action/Comments

The ready biodegradable characterization was removed and the robust summary updated to reflect that the test was conducted under acclimated conditions.

(12) 1,2-Benzenedicarboxylic acid, (C7, C9) branched and linear (CAS No. 111381-89-6);

Comment [daw22]: The biodegradability of this substance can be assessed using biodegradation data from Diiso C7 phthalate ester, CAS #71888-89-6, and Diiso C9 phthalate ester, CAS #68515-48-0.

Action/Comments

The biodegradability of this substance can be assessed using biodegradation data from Diiso C7 phthalate ester, CAS #71888-89-6, and Diiso C9 phthalate ester, CAS #68515-48-0.

(13) 1,2-Benzenedicarboxylic acid, benzyl C7-C9 branched and linear alkyl esters (CAS No. 68515-40-2);

Comment [daw23]: The biodegradability of this substance can be assessed using biodegradation data from Diiso C7 phthalate ester, CAS #71888-89-6, Diiso C9 phthalate ester, CAS #68515-48-0, and butyl benzyl phthalate ester, CAS #85-68-7.

Action/Comments

The biodegradability of this substance can be assessed using biodegradation data from Diiso C7 phthalate ester, CAS #71888-89-6, Diiso C9 phthalate ester, CAS #68515-48-0, and butyl benzyl phthalate ester, CAS #85-68-7.

(14) 1,2-Benzenedicarboxylic acid, di-C11-C14, branched alkyl esters, C13 rich(CAS No. 68515-47-9):

Comment [daw24]: A biodegradation study robust summary for this substance has been added to the dossier for this CAS number.

Action/Comments

A biodegradation study robust summary for this substance has been added to the dossier for this CAS number.

There are no acceptable data for these three chemicals or potential "read across" analogues.

Comment [daw25]: See specific comments below.

Action/Comments

See specific comments below.

(15) 1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear (CAS No. 68515-45-7)

Comment [daw26]: The biodegradability of this substance can be assessed using biodegradation data from Diiso C9 phthalate ester CAS No. 68515-48-0. A robust summary for this endpoint and substance has been added to the dossier for CAS No. 68515-48-0.

Action/Comments

The biodegradability of this substance can be assessed using biodegradation data from Diiso C9 phthalate ester CAS No. 68515-48-0. A robust summary for this endpoint and substance has been added to the dossier for CAS No. 68515-48-0.

(16) 1,2-Benzenedicarboxylic acid, di-C9-C11 branched and linear alkyl esters (CAS No. 68515-43-5)

Comment [daw27]: The biodegradability of this substance can be assessed using biodegradation data from Diiso C9 phthalate ester, CAS #68515-48-0 and Diiso C11 phthalate ester, CAS #3648-20-2.

Action/Comments

The biodegradability of this substance can be assessed using biodegradation data from Diiso C9 phthalate ester, CAS #68515-48-0 and Diiso C11 phthalate ester, CAS #3648-20-2.

(17) 1,2-Benzenedicarboxylic acid. di(C11) ester, branched and linear (DIUP, CAS No. 85507-79-5)

Comment [daw28]: The biodegradability of this substance can be assessed using biodegradation data from Diiso C11 phthalate ester, CAS #3648-20-2.

Action/Comments

The biodegradability of this substance can be assessed using biodegradation data from Diiso C11 phthalate ester, CAS #3648-20-2.

(18) 1.2-Benzenedicarboxylic acid, (C9, C11) ester, branched and linear (CAS No. 111381-91-0):

Comment [daw29]: The biodegradability of this substance can be assessed using biodegradation data from Diiso C9 phthalate ester, CAS #68515-48-0 and Diiso C11 phthalate ester, CAS #3648-20-2.

Action/Comments

The biodegradability of this substance can be assessed using biodegradation data from Diiso C9 phthalate ester, CAS #68515-48-0 and Diiso C11 phthalate ester, CAS #3648-20-2.

There are no acceptable data on these chemicals or on any analogues. The Carson et al. data obtained by EPA for CAS No. 111381-90-9 cannot be applied to these chemicals because the uncertainty of the method used (die-away test) is too great and because of the wide range of alkyl functionality (C7-11) in CAS No. 111381-90-9.

Comment [daw30]: Select data have been identified that can provide adequate read-across data for all substances above.

Action/Comments

Select data have been identified that can provide adequate read-across data for all substances above.

Fugacity. The submitter uses the Level I fugacity model in EQC (version 1.01) to determine the partitioning behavior of the test substances. No details on the model input were provided in the test plan or in the robust summary.

Comment [daw31]: Details on model input were added to all robust summaries for the Level I EQC calculations.

Action/Comments

Details on model input were added to all robust summaries for the Level I EQC calculations.

Measured physical properties are preferred for this model, and when actual data are available they should be used in place of estimated values.

Comment [daw32]: Physical property robust summaries needed for Level I/III fugacity modeling were updated and only the critical data as identified in the summary were used to model fugacity. The physical property data included measured and calculated values and were selected by industry, peer reviewed, as the correct values to use for the relevant endpoint.

Action/Comments

Physical property robust summaries needed for Level I/III fugacity modeling were updated and only the critical data as identified in the summary were used to model fugacity. The physical property data included measured and calculated values and were selected by industry, peer reviewed, as the correct values to use for the relevant endpoint.

Level III (EPIWIN) modeling results generated by EPA indicate that the transitional and HMW phthalates will be distributed mainly to sediment but

also significantly to soil, while the LMW phthalates will be distributed mainly to soil and also significantly to water. These results differ from those calculated by the submitter; their estimations indicate that the HMW and transitional phthalates will be distributed mainly to soil. The sponsor indicates that there are sufficient data for this endpoint based on results from a Level I fugacity model and that additional work is not recommended. Although the HPV Challenge Program accepts Level 1 fugacity modeling to estimate transport/distribution values, the EPA believes that values based on a Level III fugacity model are more realistic and useful for estimating a chemical's fate in the environment on a regional basis.

Comment [daw33]: New robust summaries for the Level III EQC calculations were prepared for all substances in this category. Modeling input details were included in the robust summaries.

Action/Comments

New robust summaries for the Level III EQC calculations were prepared for all substances in this category. Modeling input details were included in the robust summaries.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Although there were some inconsistencies in the submission, data on sponsored phthalates plus data on analogous phthalates satisfy all health effects endpoints for the purposes of the HPV Challenge Program.
Repeated-dose Toxicity. Overall data are adequate for the purposes of the HPV Challenge Program. For di-C9-C11 phthalates, supporting data are on an unidentified analogue. The submitter needs to identify the analog.

Comment [anb34]: Supporting data for di-C9-C11 phthalates are on DINP and DIDP. The test plan has been updated to clarify this point.

Action/Comments

Supporting data for di-C9-C11 phthalates are on DINP and DIDP. The test plan has been updated to clarify this point.

Another option is to use the adequate repeated-dose data from the di-C9-C11 phthalates reproductive toxicity study.

Genetic Toxicity. Overall data are adequate for the purposes of the HPV Challenge Program. However, for DIOP, the adequacy of a negative mutagenicity assay in bacteria could not be determined from the information provided in the robust summary.

Comment [anb35]: Additional information has been added to the test plan and robust summary for DIOP. The information is now adequate to support the negative result.

Action/Comments

Additional information has been added to the test plan and robust summary for DIOP. The information is now adequate to support the negative result.

Ecological Effects (fish, invertebrates, and algae)

The submitter provided summaries of studies on some category and analogous chemicals. Some of the submitted data for groups II and III are not reliable because endpoints were tested above the chemical's water solubility, and test durations (acute) were too short for chemicals whose calculated log Kow is > 4.2. Only acute studies tested close to the chemicals' water solubility were considered key studies by EPA and commented on for data adequacy. Testing was performed for both branched and linear forms of the transitional and HMW phthalates. The submitter should discuss whether or not differences in toxicity are expected between these forms.

Comment [daw36]: The extant aquatic toxicity database for the phthalates within the Transitional and High molecular weight subcategories support characterizing branched and linear forms as similar, ie, not acutely or chronically toxic. A short discussion to this effect was added to the test plan.

Action/Comments

The extant aquatic toxicity database for the phthalates within the Transitional and High molecular weight subcategories support characterizing branched and linear forms as similar, ie, not acutely or chronically toxic. A short discussion to this effect was added to the test plan.

Fish, Invertebrates, and Algae.

Acute and chronic toxicity data are adequate for one or more category phthalates in each of the three subdivisions except for three transitional phthalates. Because the calculated log Kow values for DHP, diheptyl phthalate, and diisoheptyl phthalate are more than one log unit lower than that for the analogue DEHP, chronic toxicity may be observed. EPA suggests that one of these transitional phthalates undergo a chronic daphnid test.

Comment [daw37]: Invertebrate and/or fish chronic data are available for dihexyl phthalate and diisoheptyl phthalate. Robust study summaries have been prepared and added to respective dossiers for these substances. Additionally, fish chronic robust study summaries for di-C711 phthalate ester and di-C11 phthalate ester were also added to their respective dossiers.

Action/Comments

Invertebrate and/or fish chronic data are available for dihexyl phthalate and diisoheptyl phthalate. Robust study summaries have been prepared and added to respective dossiers for these substances. Additionally, fish chronic robust study summaries for di-C711 phthalate ester and di-C11 phthalate ester were also added to their respective dossiers.

The submitter may want to do a water solubility test first to identify the most water-soluble chemical for optimum test design. If a carrier is used, the carrier concentration should be #100 mg/L; however, an emulsifier should not be used.

The test should be conducted under flow-through conditions using mean measured concentrations.

Comment [daw38]: The chronic fish studies for dihexyl, di-C711, and di-C11 were conducted under flow-through conditions.

Action/Comments

The chronic fish studies for dihexyl, di-C711, and di-C11 were conducted under flow-through conditions.

The submitter indicated that the use of solvent in the algal tests made them invalid. EPA considers the use of solvent to enhance chemical solubility acceptable as long as the solvent and the amount follow those specified in the Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (http://www.oecd.org./ehs/test/monos.htm). These data may be useful and EPA recommends the submission of robust summaries for these studies.

Comment [daw39]: Previously submitted alga study robust summaries were enhanced and new alga summaries added to select dossiers. Sufficient data now exist to characterize this endpoint for the entire category.

Action/Comments

Previously submitted alga study robust summaries were enhanced and new alga summaries added to select dossiers. Sufficient data now exist to characterize this endpoint for the entire category.

Specific Comments on the Robust Summaries

Health Effects

Seventy-two robust summaries were reviewed. For each endpoint, summaries were submitted for at least one chemical in each of the three groups. In general, the robust summaries provided sufficient information to evaluate the studies, and only a few contained errors or confusing study descriptions. The quality of the reviewed studies was good, as most were carried out under GLP/OECD or similar guidelines.

The submitter did not provide any health effects data for three HMW phthalates: 610P, didecyl phthalate, and DIUP.

Comment [anb40]: Health effects data are not presented for the identified HMW phthalates because 1) the data are unavailable and 2) C6, C8, and C7-11 phthalates are considered appropriate sources for read across.

Action/Comments

Health effects data are not presented for the identified HMW phthalates because 1) the data are unavailable and 2) C6, C8, and C7-11 phthalates are considered appropriate sources for read across.

In addition, robust summaries were not provided for two transitional analogues, dibutyl phthalate (DBP; CAS No. 84-74-2) and DEHP, although quantitative values for all health effects endpoints were included in Table 3 of the Test Plan.

Comment [anb41]: Robust summaries for the reproductive and developmental effects for DEHP were added to the diisooctyl dossier as these data were key in supporting these endpoints. All other data obtained from studies using DBP and DEHP were removed from the test plan as there is adequate data from phthalates composing the transitional phthalate category to cover all other endpoints via read across.

Action/Comments

Robust summaries for the reproductive and developmental effects for DEHP were added to the diisooctyl dossier as these data were key in supporting these endpoints. All other data obtained from studies using DBP and DEHP were removed from the test plan as there is adequate data from phthalates composing the transitional phthalate category to cover all other endpoints via read across.

These omissions are especially important as the two analogues are prominent in the Test Plan. Finally, robust summaries were not provided for acute oral toxicity data on DEP, DIOP, and DUP.

Comment [anb42]: Please See comments 43and 45.

Action/Comments

Please see comments below.

Acute toxicity. Sixteen robust summaries were reviewed.

DEP.

The submitter needs to provide a robust summary for this endpoint.

Comment [anb43]: Table 3 of the test plan states that the robust summary can not be prepared due to insufficient information. This has been confirmed in that the values originated from a 1957 Russian document. Therefore, a robust summary for this endpoint can not be created.

Action/Comments

Table 3 of the test plan states that the robust summary can not be prepared due to insufficient information. This has been confirmed in that the values originated from a 1957 Russian document. Therefore, a robust summary for this endpoint can not be created.

Di-n-hexyl phthalate.

In the robust summary for the rat acute oral study, the LD50 values need to be converted from mL/kg to mg/kg body weight.

Comment [anb44]: Insufficient information is available concerning study design. Therefore these values cannot accurately be converted. This information does not affect the overall conclusions of the test plan.

Action/Comments

Insufficient information is available concerning study design. Therefore these values cannot accurately be converted. This information does not affect the overall conclusions of the test plan.

DIOP.

The sponsor needs to submit robust summary details from a primary source, rather than a secondary one.

Comment [anb45]: The primary source is unavailable. The information was obtained from Krauskopf, L., 1973 which cites unpublished sources.

Action/Comments

The primary source is unavailable. The information was obtained from Krauskopf, L., 1973 which cites unpublished sources.

Repeated-dose toxicity. Twelve robust summaries were reviewed.

DMP.

A robust summary for a 90-day dermal toxicity study in rabbits was incomplete, but it provided sufficient information to evaluate the study. The original study did not report the doses administered, the strain and sex of rabbit, information on the control group or the frequency or method of treatment. Other omissions included the substance purity, group size, mortality and body weight effects, and precise NOAEL and LOAEL values (kidney and lung effects occurred at the two highest dose levels, but the summary only specified the highest dose).

Comment [anb46]: Insufficient information exists from the original study to support any added value above what has already been included in the robust summary. The frequency of treatment was determined to be once daily for the duration of the testing.

Action/Comments

Insufficient information exists from the original study to support any added value above what has already been included in the robust summary. The frequency of treatment was determined to be once daily for the duration of the testing.

The study pre-dated GLP and OECD guidelines. Despite reporting deficiencies, the study appears to be marginally adequate based on the extensive histopathological analysis (7,000 individual tissues examined) and the identification of target organs.

Di-C7-C9 phthalates.

Robust summaries of subchronic feeding assays in rats and dogs are inadequate because the analogue used (i.e., the test material) was not defined and only the study NOAEL's were reported.

Comment [anb47]: The original subchronic feeding study in rats and dogs is unavailable. This information does not affect the major conclusions laid out in the test plan.

Action/Comments

The original subchronic feeding study in rats and dogs is unavailable. This information does not affect the major conclusions laid out in the test plan.

Genetic Toxicity. Sixteen summaries of gene mutation studies and seven summaries of chromosomal aberration studies were reviewed.

Diheptyl phthalate.

A robust summary for a negative GLP/OECD guideline mutation assay in cultured mouse lymphocytes provided sufficient information to evaluate the study, but it was incomplete. The test material was phthalate mixture 711P (containing no more than 15% diheptyl phthalate), but the summary did not report the compositional basis.

Comment [anb48]: The robust summary has been updated to add more detail to define the test substance; however, the compositional analysis for the test material is unavailable.

Action/Comments

The robust summary has been updated to add more detail to define the test substance; however, the compositional analysis for the test material is unavailable.

Di-C9-C11 (C10-rich) branched alkyl esters of 1,2-benzenedicarboxylic acid (CAS No. 68515-49-1).

A robust summary for a negative mutation assay in Salmonella typhimurium did not provide sufficient information to evaluate the study. Omissions included the purity and identity of the test material, the number of replicates, the specific concentrations tested (only a range was reported), the cytotoxic concentration, and positive controls (if used).

Comment [a49]: The robust summary has been updated to include the previously omitted information.

Action/Comments

The robust summary has been updated to include the previously omitted information.

The study is probably adequate since it followed the standard Ames methods (the basis for OECD guideline 471); negative mutagenicity data are supported by similar results in the mouse lymphoma assay (not reviewed). A robust summary for a negative micronucleus assay in mice exposed by gavage provided sufficient information to evaluate the study, but omitted the group size, gavage vehicle, number of cells examined, positive control use, and the specific procedural modifications.

Comment [anb50]: The robust summary has been updated to include the group size, gavage vehicle, number of cell examined, positive control and the specific modifications to the procedure.

Action/Comments

The robust summary has been updated to include the group size, gavage vehicle, number of cell examined, positive control and the specific modifications to the procedure.

The study followed methods similar to those that were the basis for OECD guideline 474.

Reproductive Toxicity. Nine robust summaries were reviewed. Summaries of multi generation studies did not always clearly describe results separately for each generation.

DEP.

A robust summary for a two-generation (continuous breeding) study in mice omitted the magnitude of the reported changes in organ weight and body weight gain in high-dose animals. The summary was misleading in that it did not report the parental NOAEL for the F1 adults.

Comment [anb51]: The magnitudes of change for organ and body weights have been added to the robust summary. The parental LOAEL for the F1 adults was reported. A NOAEL could not be determined; only one high dose (2.5%) was tested. Effects were seen at the high dose; therefore, the LOAEL is reported.

Action/Comments

The magnitudes of change for organ and body weights have been added to the robust summary. The parental LOAEL for the F1 adults was reported. A NOAEL could not be determined; only one high dose (2.5%) was tested. Effects were seen at the high dose; therefore, the LOAEL is reported.

(The presentation would be less confusing if the results for each generation were reported in separate paragraphs.) The summary was also misleading in stating that the compound did not affect "reproduction" and was "not a reproductive toxicant." It would have been correct to state that the compound did not affect "reproductive performance," but the increased male prostate weight (and right epididymal weight, as reported in the EPA IRIS document for DEP at http://www.epa.gov/iris/subst/0226.htm), suggests that the male reproductive tract is a target of DEP.

Comment [anb52]: Due to the observed increase in male prostate weight, the robust summary has been revised to conclude that DEP does not effect reproductive performance. All effects of DEP on reproduction are clearly stated.

Action/Comments

Due to the observed increase in male prostate weight, the robust summary has been revised to conclude that DEP does not effect reproductive performance. All effects of DEP on reproduction are clearly stated.

BBP.

A robust summary for a one-generation study in rats omitted the name of the test material.

Comment [a53]: Identification of the test material has been added to the robust summary for the 1-gen. study in rats.

Action/Comments

Identification of the test material has been added to the robust summary for the 1-gen. study in rats.

Di-n-hexyl phthalate.

A robust summary for a 14-week continuous breeding study in rats provided sufficient information to evaluate the study, but it contained some errors and omissions. The summary classed the study as a two- rather than a one-generation study.

Comment [a54]: The classification of the robust summary has been changed to indicate a 1-generation study.

Action/Comments

The classification of the robust summary has been changed to indicate a 1-generation study.

The summary was incorrect in stating that there were no changes in reproductive organs in high-dose females. Although no microscopic lesions were reported, there was a 31% decrease in uterine weight (NTP-CERHR (2000) Expert Panel review on di-n-hexyl phthalate at http://cerhr.niehs.nih.gov/CERHRchems/index.html).

Comment [a55]: The robust summary has been updated and corrected to indicate the statistically significant decrease in uterine weight in high-dose females.

Action/Comments

The robust summary has been updated and corrected to indicate the statistically significant decrease in uterine weight in high-dose females.

Di-C8-C10 (C9-rich) branched alkyl esters of 1,2-benzenedicarboxylic acid.

A robust summary for one- and two-generation studies in rats identified the highest doses as NOAEL's although toxicity was observed at these levels. Furthermore, since the summary did not clearly report the dose levels for each study, it was not always possible to determine whether reported results referred to the one- or the two-generation study.

Comment [a56]: The NOAELs reported are accurate based on the following parameters: mating, male and female fertility, fecundity, hestational index, length of gestation. There were no effects on these parameters in either the 1 or 2 generational studies.

Action/Comments

The NOAELs reported are accurate based on the following parameters: mating, male and female fertility, fecundity, hestational index, length of gestation. There were no effects on these parameters in either the 1 or 2 generational studies.

Ditridecyl phthalate.

A robust summary for a reproductive toxicity study in rats incorrectly reported the lowest test dose as a NOAEL; the live birth index was significantly reduced at that dose. The summary did not specify the basis for identification of paternal and maternal NOAEL's.

Comment [anb57]: The basis for identification of the paternal and maternal NOAEL's have been explicitly stated in the robust summary. The NOAEL reported for maternal toxicity is correct. The live birth index was significantly reduced at 250mg/kg/day and the NOAEL reported is 50 mg/kg/day.

Action/Comments

The basis for identification of the paternal and maternal NOAEL's have been explicitly stated in the robust summary. The NOAEL reported for maternal toxicity is correct. The live birth index was significantly reduced at 250mg/kg/day and the NOAEL reported is 50 mg/kg/day.

Developmental Toxicity. Twelve robust summaries were reviewed.

DEP.

A robust summary for a developmental study in rats provided sufficient information to evaluate the study, but it had some omissions and errors. The purity of the test material and the magnitude of the reductions in food consumption and body weight gain in high dose dams were not reported.

Comment [a58]: The robust summary has been updated to include the purity of the test material and the magnitude of reductions.

Action/Comments

The robust summary has been updated to include the purity of the test material and the magnitude of reductions.

The summary was inaccurate in reporting the latter as a reduction in body weight and in reporting the lowest dose tested as the fetal NOAEL. Statistically significant fetal effects (increased incidence in supernumerary ribs) were observed at this dose, thus making it the fetal LOAEL.

Comment [a59]: The NOAEL for maternal toxicity has been corrected to reflect data that show statistically significant decreases in food consumption and body weight gain in the two highest doses in the female rats.

The reported fetal NOAEL has been changed to a LOAEL in light of the statistically significant fetal effects observed.

Action/Comments

The NOAEL for maternal toxicity has been corrected to reflect data that show statistically significant decreases in food consumption and body weight gain in the two highest doses in the female rats.

The reported fetal NOAEL has been changed to a LOAEL in light of the statistically significant fetal effects observed.

Diheptyl phthalate.

A robust summary for a developmental study in rats exposed to substance 711P (no more than 15% diheptyl phthalate) provided sufficient information to evaluate the study, but it had some omissions and errors. Omissions included the gestational days of exposure, the percent composition of the test material (including the ~10% C4-C10 substances mentioned on page 18 of the test plan), and the magnitude of changes in body and organ weights.

Comment [a60]: The robust summary has been updated to include the previously omitted information.

Action/Comments

The robust summary has been updated to include the previously omitted information.

Diisoheptyl phthalate (CAS No. 71888-89-6).

A robust summary for a developmental study in rats provided sufficient information to evaluate the study but was incomplete. Omissions included the purity of the test material and details of the fetal effects noted at the highest dose.

Comment [a61]: The robust summary has been updated to include details on the fetal effects noted at the highest dose. Information on the purity of the test material was unavailable.

Action/Comments

The robust summary has been updated to include details on the fetal effects noted at the highest dose. Information on the purity of the test material was unavailable.

The increased liver weights in dams were interpreted as physiologically adaptive, but this may not be justifiable because the liver was not evaluated for histopathology. Therefore, the maternal NOAEL is likely lower than the value assigned in the summary.

Comment [a62]: The increases in liver weights were small, (16% relative liver weight increase at high dose). These increases were consistent with the known ability of certain other alkyl esters of 1,2 benzene dicarboxylic acid to cause peroxisome proliferation (Boorman et al., 1990) which supports the increased liver weights as physiological adaptations. Therefore, the NOAEL reported is considered appropriate.

Action/Comments

The increases in liver weights were small, (16% relative liver weight increase at high dose). These increases were consistent with the known ability of certain other alkyl esters of 1,2 benzene dicarboxylic acid to cause peroxisome proliferation (Boorman et al., 1990) which supports the increased liver weights as physiological adaptations. Therefore, the NOAEL reported is considered appropriate.

Ecological Effects

For fish and invertebrates, all robust summaries lacked the following study details: test substance purity, control response, signs of toxicity/mortality by concentration, 95% confidence limits, and some water chemistry parameters, including pH, amount of carrier solvent, type of carrier, hardness and alkalinity.

Comment [daw63]: Information on purity was added to all aquatic tox summaries - either the information provided in the study report or that no data was available. Available information from the reports on control response, signs of toxicity/mortality by concentration, 95% confidence limits, and some water chemistry parameters, including pH, amount of carrier solvent, type of carrier, hardness and alkalinity was added to all aquatic tox summaries.

Action/Comments

Information on purity was added to all aquatic tox summaries - either the information provided in the study report or that no data was available. Available information from the reports on control response, signs of toxicity/mortality by concentration, 95% confidence limits, and some water chemistry parameters, including pH, amount of carrier solvent, type of carrier, hardness and alkalinity was added to all aquatic tox summaries.

For algae, all robust summaries lacked the following study details: test substance purity, number of replicates per concentration, control response, and signs of toxicity per concentration.

Comment [daw64]: Information on purity was added to all alga tox summaries - either the information provided in the study report or that no data was available. Available information from the reports on number of replicates per concentration, control response, and signs of toxicity per concentration was added to alga tox summaries.

Action/Comments

Information on purity was added to all alga tox summaries - either the information provided in the study report or that no data was available. Available information from the reports on number of replicates per concentration, control response, and signs of toxicity per concentration was added to alga tox summaries.

Follow up Activity

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.